K033077

APR 3 0 2004

MTC *Media Trade Corporation*

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510(k) Summary

Submitter's Name:	Guenter Ginsberg Media Trade Corporation
Address:	11820 Red Hibiscus Drive Bonita Springs, FL 34135
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E-mail:	gg@mediatradecorp.com
Contact:	Guenter Ginsberg
Date of Summary:	September 24, 2003
Trade Name:	***easytem* duo,** Dual Thermometer, Forehead/Ear Model BT-021
Classification:	Thermometer, Clinical, Electronic Product Code: FLL Regulation No. 880.2910 Class: II Panel: 80 (General Hospital)
Predicate Devices:	Braun Thermoscan, IRT-3520 K 983295 (Predicate #1) SAAT ThermoTek 718F K 002712 (Predicate #2)

Device Description:	The ***easytem*** **duo** Forehead/Ear Thermometer is a dual purpose hand held instrument that measures body temperature on the forehead or through the opening of the auditory canal. The forehead operation is based on measuring the temperature on the surface of the forehead while the ear operation measures the natural thermal radiation emitted from the tympanic membrane and adjacent surfaces.
Intended Use:	The ***easytem*** **duo** Ear Thermometer is intended for the intermittent measurement and monitoring of human body temperature in the home. It is intended for use on people of all ages.
Technological Characteristics:	The ***easytem*** **duo** Forehead/Ear Thermometer has the same general design and performance characteristics as the predicate devices from Braun, and SAAT. The main difference is the physical size, shape and weight. The ***easytem*** **duo** Forehead/Ear Thermometer has the same intended use, general design and incorporates similar materials and components, hence should therefore raise no new questions of safety and effectiveness. This submitter concludes that the ***easytem*** **duo** Thermometer is therefore substantially equivalent in the 'ear mode' as to the predicate devices "Braun Thermoscan RT3520" and to the "ThermoTek 718F" in the 'forehead mode'.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Metatech Company Limited
C/O Mr. Guenter Ginsberg
Official Correspondent
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, Florida 34135

Re: K033077
Trade/Device Name: *easytem duo*, Forehead/Ear Thermometer, Model BT-021
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 23, 2004
Received: February 24, 2004

Dear Mr. Ginsberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K033077

DEVICE NAME: METATECH Co. Ltd., Easytem **duo,** Dual Forehead/ Ear Thermometer, Model BT-021

INDICATIONS FOR USE:

This device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal **or** on the forehead in the neonatal, pediatric and adult population used at home.

Nick Hubbard for Anthony Watson

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K033077

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109)

OR

Over-The-Counter-Use ✓ (Optional Format 1-2-96)